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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/691,823
Filing Date: October 23, 2003
Appellant(s): GREWE ET AL.

George H. Gerstman
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 10/02/2007 appealing from the Office action mailed 04/03/2007.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

The Examiner agrees with Appellant's assertion that claims 38-39 were canceled in an After Final Amendment filed 08/16/2007, but before the Appeal Brief filed 10/02/2007 and after the Pre-Brief Appeal Conference decision mailed 07/20/2007.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

The amendment after final rejection filed on 08/16/2007 has been entered as it appears to place the Application in better form for Appeal.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

2002/0165534	HAYZELDEN	10-2002
6,273,876	KLIMA	8-2001

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

1. Claims 1, 3-19, 21-23, and 25-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hayzelden et al (US 2002/0165534 A1) in view of Klima et al (US 6,273,876 B1).

2. For claims 1, 3, 4, 19, 21-23, 25, and 26, Hayzelden et al teaches a bi-directional steerable guidewire, an intravascular device, having a deflectable tip, comprising:

- an elongated flexible tubing (22) defining a lumen (28) member having proximal (26) and distal portions (24);
- a flexible helical coil (82) having multiple turns and having proximal and distal ends (as best seen in Figures 2 and 3);
- an elongated deflection member (124 and 56) having proximal and distal portions and being slidably disposed within said tubing and within said helical coil (as best seen in Figures 5 and 8), the proximal portion of the deflection member being of a cylindrical cross section and the distal portion of said deflection member being flattened to form a deflection ribbon which extends in a plane (paragraph 43);
- a retaining ribbon (54) having proximal and distal ends, the proximal end of the retaining ribbon is attached to the distal portion of the flexible tubing and the retaining ribbon is oriented to extend in a plane which is generally parallel to the plane of the deflection ribbon; and

- an attachment member (50), a rounded bead, engaging the distal end of the helical coil, the distal portion of the deflection member and the distal end of the retaining ribbon so that longitudinal movement of the deflection member in a distal direction causes the distal end of the helical coil to be deflected in one direction and longitudinal movement of the deflection member in a proximal direction causes the distal end of the helical coil to deflect in another opposite direction (as best seen in Figure 2).

3. For claims 5 and 27, Hayzelden et al teaches a bi-directional steerable guidewire having a deflectable tip, wherein the retaining ribbon and the deflection ribbon are capable of being normally biased in an arcuate configuration causing the distal end of the helical coil to be normally biased in a curved shape due to being a shape-memory metallic alloy (Hayzelden et al, paragraph 43).

4. For claims 6 and 28, Hayzelden et al teaches a bi-directional steerable guidewire having a deflectable tip, wherein the proximal portion of said deflection member is capable of being a circular cross section that extends from the proximal portion of the flexible tubing to approximately the distal portion of the tubing by not being entirely flattened (Hayzelden et al, paragraph 43).

5. For claim 7, Hayzelden et al teaches a bi-directional steerable guidewire having a deflectable tip, wherein the proximal end of said retaining ribbon extends from the distal portion of the flexible tubing to approximately the distal end of the flexible helical coil (Hayzelden et al, Figure 1).

6. For claim 8, Hayzelden et al teaches a bi-directional steerable guidewire having a deflectable tip, wherein the attachment member takes the form of a rounded bead (50).

7. For claim 9, Hayzelden et al teaches a bi-directional steerable guidewire having a deflectable tip, wherein the rounded bead is formed with an epoxy material (Hayzelden et al, paragraph 30).

8. For claims 10 and 29, Hayzelden et al teaches a bi-directional steerable guidewire having a deflectable tip, wherein the attachment member takes the form of a rounded bead (50) which contacts the distal end of the helical coil to define a circular surface at the distal end of the coil and the deflection ribbon (56) engages the rounded bead at a location offset from the center of the circular surface of the rounded bead (Hayzelden et al, Figures 6 and 10).

9. For claims 11 and 30, Hayzelden et al teaches a bi-directional steerable guidewire having a deflectable tip, wherein the distal end of the retaining ribbon engages the rounded bead at a location offset from the center of the circular surface of the rounded bead (Hayzelden et al, Figures 6 and 10).

10. For claims 12 and 31, Hayzelden et al teaches a bi-directional steerable guidewire having a deflectable tip, wherein the distal end of the retaining ribbon engages the rounded bead at a location offset from the center of the circular surface in an opposite direction from the offset location of the deflection ribbon (Hayzelden et al, Figure 6).

11. For claims 13 and 32, Hayzelden et al teaches s a bi-directional steerable guidewire having a deflectable tip, wherein the deflection member and the retaining

ribbon are joined to each other within the rounded bead (Hayzelden et al, Figures 2 and 5).

12. For claim 14, Hayzelden et al teaches a bi-directional steerable guidewire having a deflectable tip, wherein the deflection ribbon and the retaining ribbon are formed as a single unitary element (54).

13. For claims 15 and 33, Hayzelden et al teaches a bi-directional steerable guidewire having a deflectable tip, wherein the deflection ribbon and the retaining ribbon are joined to form a generally U-shaped configuration (54) to thereby provide a predetermined spacing between the deflection ribbon and the retaining ribbon and to maintain the deflection ribbon and the retaining ribbon in planes which are parallel to each other (Hayzelden et al, Figures 2, 5 and 6).

14. For claims 16 and 34, Hayzelden et al teaches a bi-directional steerable guidewire having a deflectable tip, wherein the deflection ribbon is formed by flattening an intermediate portion of the deflection member and the retaining ribbon is formed by flattening a distal portion of the deflection member (Hayzelden et al, paragraph 43).

15. For claims 17 and 35, Hayzelden et al teaches a bi-directional steerable guidewire having a deflectable tip, wherein the retaining ribbon is capable of having a thickness that is less than the thickness of the deflection ribbon via extra flattening (Hayzelden et al, paragraph 43).

16. For claim 18, Hayzelden et al teaches a bi-directional steerable guidewire having a deflectable tip, wherein the deflection ribbon is capable of having a thickness of .002 inches and the retaining ribbon is of a thickness of .0015 inches.

17. For claim 36, Hayzelden et al teaches a bi-directional steerable guidewire having a deflectable tip, wherein the proximal portion of the elongated flexible tubing is coupled to a control handle (42) and the elongated deflection member is mounted with the control handle for longitudinal movement (Hayzelden et al, Figure 1).

For claim 37, Hayzelden et al discloses a bi-directional steerable guidewire having a deflectable tip, wherein said control handle includes a movable knob (78) that is coupled to the elongated deflection member for longitudinal positioning of the deflection member.

18. Thus for 1, 3-19, 21-23, and 25-39, Hayzelden et al teaches the claimed invention except for expressly disclosing the helical coil having a rectangular cross-sectional configuration and having continuous undulations, wherein the undulations of adjacent turns interlock with each other in order to enhance the rotational rigidity of the coil and wherein the undulations take the form of a sinusoidal wave and a square sinusoidal wave having positive and negative peaks and in which the positive peaks of adjacent turns of coils engage negative peaks of adjacent turns; wherein the helical coil has a square cross-sectional configuration; the proximal end of said helical coil is attached to the distal portion of the flexible tubing; and wherein said undulations are lateral to the length of the elongated flexible tubing.

19. Klima et al teaches a catheter, an intravascular device, having a helical coil (72i) having a rectangular cross-sectional configuration and having continuous undulations wherein the undulations of adjacent turns interlock with each other in order to enhance the rotational rigidity of the coil and wherein the undulations take the form of a

sinusoidal wave (as best seen in Figures 11A, 11B, 12A, 12B and 15) and a square sinusoidal wave (as best seen in Figures 13A, 13B, and 15) having positive and negative peaks (created by fingers 1077) and in which the positive peaks of adjacent turns of coils engage negative peaks of adjacent turns (column 11 lines 26-30); wherein the helical coil has a square cross-sectional configuration; the proximal end of said helical coil is attached to the distal portion of the flexible tubing; and wherein said undulations are lateral to the length of the elongated flexible tubing (column 10 lines 25-58 and as best seen in Figures 13B and 15).

20. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the intravascular device as taught by Hayzelden et al, with the helical coil configuration as taught by Klima et al for the purpose of and to achieve the predictable results of increasing the efficacy of an intravascular device to navigate tortuous vasculature.

(10) Response to Argument

21. Appellant's arguments filed 10/02/2007 have been fully considered but they are not persuasive. Appellant argues the obviousness type rejection of claims 1, 3-19, 21-23, and 25-37 as being unpatentable over Hayzelden et al in view of Klima et al, as set forth in the Final rejection mailed 04/03/2007 and reiterated above.

22. For claims 1, 3-18, 23, and 25-37, Appellant argues (a) that both Hayzelden et al and Klima et al are inapplicable to the invention as claimed because they are not concerned with "a steerable guidewire" (see Appeal Brief filed 10/02/2007, page 6 paragraph 4 – page 8 paragraph 2); (b) that Hayzelden et al does not disclose "a

flexible helical coil having multiple turns" (see Appeal Brief filed 10/02/2007, page 8 paragraphs 3-5); and (c) that Klima et al does not remedy the deficiencies of Hayzelden et al because Klima et al does not teach a coil having "undulations taking the form of a sinusoidal wave having positive and negative peaks and in which the positive peaks of adjacent turns of coils engage negative peaks of adjacent turns" (see Appeal Brief filed 10/02/2007, page 9 paragraph 1 – page 10 paragraph 3).

23. For claims 19, 21, and 22, Appellant argues (a) as set forth above; (b) as set forth above; (c) as set forth above; and (d) that Klima does not disclose "a rounded bead" (see Appeal Brief filed 10/02/2007, page 12 paragraph 2).

24. In response to Appellant's arguments, the Examiner disagrees, maintains the rejection as reiterated above, and notes the following in response:

25. In response to applicant's arguments (a) that both Hayzelden et al and Klima et al are inapplicable to the invention as claimed because they are not concerned with "a steerable guidewire", the Examiner notes that both catheters and guidewires are intravascular devices for navigating tortuous vasculature during advanced medical procedures. As claimed, a "steerable catheter" is not only capable of performing the functions of a "steerable guidewire", but the "steerable guidewire" of at least claims 1 and 23 is "an elongated flexible tubing" as opposed to a singular wire structure for instance. The Examiner notes, that in rejecting the structure of claims 1, 19, and 23 under the broadest reasonable interpretation, the claim language does not preclude the application of a "a catheter" based prior art apparatus because the claimed limitations read on an a device comprising *inter alia* an elongate tubular member, a helical coil

disposed thereon, a deflection member, a retaining ribbon, and an attachment member. In addition, Appellant's arguments (see Appeal Brief filed 10/02/2007, page 6 paragraph 4 – page 8 paragraph 2) appear to be directed to the intended use of the "steerable guidewire" and to functional limitations which are not claimed.

26. In response to applicant's arguments (b), that Hayzelden et al does not disclose "a flexible helical coil having multiple turns", the Examiner notes that the cited "flexible helical coil" (82) of Hayzelden is a plurality of flexible helical coils having multiple turns and comprising a braid. The positively identified structure of Hayzelden is structurally equivalent to the claimed "flexible helical coil having multiple turns". The Examiner notes, that in rejecting the structure of claims 1, 19, and 23 under the broadest reasonable interpretation, the claim language does not preclude the application of a "a braid" because the claimed limitations read on an a device comprising *inter alia* an elongate tubular member with a helical coil disposed thereon. Hayzelden et al discloses a plurality of flexible helical coils having multiple turns. In addition, Appellant's arguments (see Appeal Brief filed 10/02/2007, page 6 paragraph 4 – page 8 paragraph 2) appear to be directed to the intended use and/or function of the "flexible helical coil".

27. In response to applicant's arguments (c), that Klima et al does not remedy the deficiencies of Hayzelden et al because Klima et al does not teach a coil having "undulations taking the form of a sinusoidal wave having positive and negative peaks and in which the positive peaks of adjacent turns of coils engage negative peaks of adjacent turns", the Examiner notes Klima teaches a helical coil (as best seen in Figures 11A, 11B, 12A, 12B and 15) having a rectangular cross-sectional configuration

and having continuous undulations wherein the undulations of adjacent turns interlock and engage each other in order to enhance the rotational rigidity of the coil and wherein the undulations take the form of a sinusoidal wave and/or a square sinusoidal wave having positive and negative peaks (created by fingers 1077) and in which the positive peaks of adjacent turns of coils engage negative peaks of adjacent turns (column 11 lines 26-30).

28. In response to applicant's arguments (d), that Klima does not disclose "a rounded bead", the Examiner notes that in the Final rejection of the claims Klima was not relied upon to teach and/or disclose "a rounded bead". Appellant apparently erroneously mischaracterized the structure of Klima cited and relied upon in the Final rejection in arguing Klima does not disclose "a rounded bead".

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/J.H./
Jeffrey G. Hoekstra
Examiner, Art Unit 3736

Conferees:

Max Hindenburg

Stephen Garbe